Comprehensive Functional Specifications and Design for IT Support of Clinical Research at an Academic Medical Center

Corey B Smith, PhD, George Kim, MD, Karen Assar, MLS, Susan Barned, MS, MLS, Adam Rothschild, MD, Robert E Miller, MD
Division of Health Sciences Informatics, School of Medicine, The Johns Hopkins University, Baltimore, MD

ABSTRACT

We present a framework for understanding and developing an Information Technology (IT) infrastructure for human subject research. First, we review the process of clinical research in an academic medical center. Next,we describe the entities ,roles,and functional relationships within the clinical research enterprise to define a conceptual data model. Finally, we address design and implementation issues for an IT infrastructure that can be adapted to the local needs of research institutions.

STATEMENT OF PROBLEM

Many large academic medical centers do not have the support of integrated information systems to manage the clinical research enterprise. The ethical and legal requirements of human subject research in the electronic age now make the judicious use of IT both logical and necessary. However, IT support for the institutional management of the research enterprise has received scant attention in the medical informatics literature.

A REGULATORY PERSPECTIVE OF CLINICAL RESEARCH

In order to understand the research process from a federal regulatory perspective we review the major steps (see below) in the design and conduct of clinical research:

1. Personnel credentialing
2. Develop research plan
3. Initiate IRB review process
4. Funding and payment arrangements
5. Subject recruitment
6. Subject enrollment
7. Protocol execution
8. Safety monitoring
9. Data sharing arrangements and analysis
10. Publication
11. Data ownership and archiving
12. Technology transfer

The DHHS "Common Rule" (45 CFR 46), FDA, and HIPAA regulations all provide independent but overlapping guidance to the range of activities represented by each of these stages.

A UML-BASED FRAMEWORK FOR MODELING REQUIREMENTS FOR IT SUPPORT OF CLINICAL RESEARCH

The specification of an IT infrastructure for clinical research begins with a representation of key entities within the enterprise, their roles and relationships to each other and to outside entities. With the protocol at the center, the following collaboration diagram (see Figure 1) characterizes the primary set of relationships intrinsic to the process of clinical research.

Figure 1. Collaboration diagram of clinical research objects and activities